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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION N |
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| 10/035,037 | 12/28/2001 | Daniel L. Cox | ACS 58088 | 9178 |
| 24201 | 7590 | 10/27/2004 | EXAMINER | |
| FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045 | | | HO, UYEN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,037

Applicant(s)

COX, DANIEL L.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/14/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 8 and 10-81 is/are pending in the application.
- 4a) Of the above claim(s) 34-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8, 10-33, 80 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 6, 8, 10-15, 17, 19-23, 26, 27, 31-33, 80 and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by Golds (6,312,458).

In regard to claim 1, Golds discloses a plurality of metallic rings (4) and a polymeric coil (20) as claimed (see figure 4).

In regard to claim 2 and 3, the rings are attached to the outer and inner surface of the coil as the coil interwoven between stent (fig. 4).

In regard to claim 6, the rings and the coil are continuously coupled together in both expanded and unexpanded stage (fig. 4, inherent).

In regard to claim 8, the rings are attached to the coil with a bonding agent (the coil 20 continuously adhered throughout its entire length or at selected areas col. 6, lines 25-52).

In regard to claim 10, the coil radially compresses when stent is crimped onto a catheter and radially expands when the stent is deployed (inherent).

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In regard to claims 11, 20-23, 26, 27, and 31-33 the stent is made from the materials as claimed (see col. 4, lines 49-64).

In regard to claim 12, the coil is made from the materials as claimed (see col. 5, line 59 to col. 6, line 9).

In regard to claims 13-15 and 17-19 the stent have undulation comprising peaks and valleys and the coil bonded to the stent at points in between the peaks and valleys (see fig. 4). The peaks and valleys form U shaped or W shaped portions and the peaks of each ring are axially aligned with the peaks of each adjacent cylindrical ring (see figs. 4). The peaks of each ring are axially aligned with the valleys of each adjacent ring (figs. 1-3)

In regard to claims 80, 81, the coil being elastically expandable in a radial direction (inherent) and wherein less than 5% the metal of the metallic cylindrical rings overlaps with less than 30% of the coil (fig. 4).

3. Claims 1-3, 6, 8, 10-27, 33, 80 and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by Kocur (6,350,277).

In regard to claim 1, Kocur disclose a stent (figure 7) including a plurality of metallic rings and a polymeric coil (1 15).

In regard to claims 2 and 3, Kocur disclose the coil attached on the outside surface of the stent or being interwoven around the circumference of the stent, weave in-between struts (col. 4, lines 14-17) or inside of the stent (col. 5, line 66 to col. 6, line 4). In regard to claim 6: the rings and the coil as disclosed by Kocur are continuously

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coupled together in both the first delivery diameter and second implanted diameter (col. 6, lines 61-67, figures 13a-13d).

In regard to claim 8, wherein the rings are attached to the coil with a bonding agent (col. 6, lines 5-60).

In regard to claim 10, wherein the coil radially compresses when the stent is crimped onto a catheter (col. 6, lines 5-60).

In regard to claims 11 and 12, the rings and coil are made from the materials as claimed (col. 8, line 61-67 and col. 7. lines 1-60).

In regard to claims 13, 15-23, 15-23, wherein the rings have configurations and are made from the material as claimed (figures 7-9, col. 8, lines 61-67).

In regard to claim 14, the rings are bonded to the coil at points in between the peaks and valleys of the rings (see alternative points of connection between the rings and the coil in figures 13a-13d).

In regard to claims 24-27 and 33, the coil is treated/coated with therapeutic agents (col. 8, lines 12-60) and the stent is made from non-biodegradable and biocompatible material (col. 8, line 61 to col. 9, line 10, see the materials of the patents that are incorporated).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 16, 24, 25, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golds (6,312,458) in view of Kocur (6,350,277). Golds discloses all the limitations of the claims except for the presence of:

- a Y shaped portion of the stent,
- coil loaded with a therapeutic drug
- coil being translucent, comprising with material that enhance the radiopacity of the stent

In regard to the Y shaped portion of the stent, Kocur disclose a stent including plurality of ring including a connecting member extending from a peak of a ring to a peak of an adjacent ring. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a connecting member between the rings of Golds' stent in order for connecting the rings together. Doing so would create a stent with Y shaped portion.

In regard to the coil loaded with a therapeutic drug, Kocur discloses a stent with coil coated/treated with therapeutic agents for a better treatment at a treated site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ therapeutic drug into Golds' coil in order to provide a better treatment at a treated site when using the stent.

In regard to the coil with radiopaque material, it is well known in the art to dispose radiopaque material on the stent to enhance the radiopacity of the stent for locating and navigating the stent to a treated site in body lumen. Therefore, it would have been

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obvious to one having ordinary skill in the art at the time the invention was made to make the coil from or coated the coil with translucent material in order to enhance the radiopacity of the stent for locating and navigating the stent to a treated site in body lumen.

6. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur (6,350,277). Although Kocur fails to disclose the rings or the coil including material therein to enhance the radiopacity of the stent, it is known in the art to locate and navigate the stent to a treated site in a body lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ radiopaque material on the coil in order to enhance the radiopacity of the stent for locating and navigating the stent to a treated site in a body lumen.

Response to Arguments

7. Applicant's arguments filed 6/14/04 have been fully considered but they are not persuasive. Applicant argues that the polymer coil retaining the stent has a first diameter, but does not have second diameter because it is designed to rupture when the stent expands. Examiner disagrees. The polymer coil (115) of Kocur reference has a second diameter before it ruptures (see col. 7, line 54 to col. 8, line 11). When the coil is ruptured at a predetermined force, it still inherently links at least some of the metallic cylindrical rings since the coil adhered to the rings. Therefore, the polymer coil of Kocur reference meets the limitations of the claimed invention.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

October 19, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

10/25/04